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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,903	03/30/2001	Daniel J. Balbierz	13724-844	7575

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,903

Applicant(s)

BALBIERZ ET AL. *CR*

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-21-01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-13, 15-31, 34-41, 50-51, 75-82 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 32, 33, 42-49 and 52-74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-13, 15-31, 35-41, 50, 51, and 75-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. ('847).

Independent claims 1,13,15,16,17,20,27,35,81,82

Gough et al. (Gough) discloses a tissue biopsy and treatment apparatus for detecting and treating tumors especially in figure 3, the apparatus comprising:

- an elongated delivery device (10) including a lumen (14);
- a deployable sensor array (24) including a plurality of resilient members (18) deployable with curvature (see figure 3), the sensor array having a geometric configuration (depicted in figure 3) adapted to volumetrically sample tissue at a tissue site or multiple tissue sites to differentiate or identify tissue including tumor boundaries (col. 4:63-67) at the tissue site(s) during an energy delivery interval (col. 6: 28-33);
- an energy delivery device (12,14,16, 20) coupled to (or comprising) the resilient members (18);

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logic resources or processor (38, fig. 9, 50. fig. 10) coupled to a power source (20), the logic resources configured to identify or differentiate tissue (through sensed temperature or impedance values) responsive to a signal from the sensor (col. 10:2-4).

Re: claim 27, Gough discloses an optical sensor member (24, col. 6: 36-38, "fiber optics").

Re: claim 35, Gough's disclosure of distinguishing tumor boundaries is equivalent to disclosure of distinguishing between healthy and abnormal tissue.

Re: claim 81, Gough discloses a rigid advancement device (14, col. 5:5-8) and a handpiece (col. 6:2-4).

Dependent claims

Re: claims 2, Gough implicitly discloses three resilient members in figure 4.

Re: claim 3, Gough discloses a substantially spherical ovoid sample volume in figure 3.

Re: claims 9-11, Gough discloses logic resources (38, fig. 9) configured to graphically display the position of the energy delivery device relative to the tumor mass (36, fig. 9, col. 10:33-39).

Re: claim 12, Gough discloses logic resources (attached to sensors 24) configured to identify a clinical endpoint for tissue ablation procedure in column 6 lines 27-34, especially, "(iii) whether or not further ablation is needed."

Re: claims 18-19, Gough discloses in figure 3, resilient members with "different directions of travel." Further, the polyamide resilient members (18) are described as

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being "semi-rigid" in column 5 lines 63-64. Inherently, this disclosure is equivalent to disclosure of members with an elastic modulus sufficient to produce a changing direction of travel (the ability to bend) in response to a force applied by tissue.

Re: claim 21, the sensors (24) attached to the energy delivery device (16) are positionable or deployable within the lumen (14) as disclosed in column 4 lines 47-52.

Re: claims 22-26, 40, Gough discloses optical sensor members or detectors (24, col. 6: 36-38, "fiber optics") inherently coupled to a light source and positionable within the lumen of the resilient members as depicted in figure 3.

Re: claims 28-29, the disclosed Gough sensors (24) detect changes in tissue properties such as temperature and impedance. Note column 6 lines 42-44.

Re: claims 30, 31, and 37, Gough discloses detection of cell necrosis volume (amount of tissue ablated). Note column 6 lines 28-34.

Re: claims 38, 39, and 41, Gough depicts in figure 3, first and second sensors (24) positioned at a greater radial distance with respect to a longitudinal axis of the elongated delivery device (10) than the energy delivery devices (16).

Re: claim 50, Gough discloses infusion capabilities (fig. 6(c), col. 9 lines 18-30.

Re: claim 51, Gough discloses four resilient members in figure 8. Although only one resilient member (18) is illustrated, Gough discloses that the members can be positioned around an exterior of one or both of the primary (14) and secondary antennas (16). Note column 5 lines 52-54. In other words, Gough implicitly discloses that the resilient members could be positioned around the exterior of all of the four

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secondary antennas (16) illustrated in figure 8, thereby resulting in four resilient members.

Re: claims 75 and 76, Gough discloses electrodes (col. 4:42-44) connected to an RF energy source (20, col. 6:8-10).

Re: claims 77-79, Gough discloses an energy delivery device (12,14,16,20) comprising a portion of the resilient members (18) as depicted in figure 3. Again, element 16 is an electrode configured to an RF energy source (20). Further again, Gough discloses a rigid advancement device (14, col. 5:5-8) and a handpiece (col. 6:2-4).

Re: claim 80, Gough discloses that each resilient member (18) can be adjustably positioned so that the length of the electrode (16) can be varied (col. 5:54-56). This is equivalent to disclosing several advancement devices (18) positionable within the elongated delivery device (10), the advancement devices (18) configured to advance independent of each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough.

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Gough neglects to disclose specific temperature ranges. However, optimal values could be discerned by routine experimentation. The motivation would be to provide temperature values that would yield successful results.

Allowable Subject Matter

Claim 14 is allowed. The prior art neglects to anticipate or provide motivation for the method disclosed in claim 14 which includes measuring a spectral profile of a tissue site to differentiate tissue at the tissue site.

Claims 4-5, 32, 33, 42-49, and 52-74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

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Pete Vrettakos

November 25, 2002

PV

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER